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EXAMINER

RAO, M

ART UNIT

PAPER NUMBER

1652

12

DATE MAILED:

12/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/339,159

Applicant(s)

Kauppinen et al.

Examiner

Manjunath N. Rao

Group Art Unit

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☒ Responsive to communication(s) filed on Oct 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-31 is/are pending in the application

Of the above, claim(s) 4-8, 12, 15-19, 30, and 31 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 9-11, 13, 14, and 20-29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-31 are still at issue and are present for examination.

Election/Restriction

2. Applicant's election with traverse of Group I, Claims 1-3, 9-11, 13, 14, 20-29 and 31, and species election of mannase with SEQ ID NO:2, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that coexamination of all of Groups I-V would not be a serious burden to the Examiner. This is not found persuasive because while the searches for the three groups overlap, they are not coextensive. The search for Groups I, II, III, IV and V would each require the search of subclasses unnecessary for the search of elected Group I. For example, search of Group I would require search of subclass 200 and search of Group II or III would require search of subclasses 252.3 or 277.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-8, 12, 15-19, and 30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 11. Furthermore claim 31 is also withdrawn from consideration as it does not involve the elected species, mannase with SEQ ID NO:2.

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Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. Acknowledgment is also made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Objections

4. Claim 14 is objected to because of the following informalities: Claim 14 depends from a non-elected claim (claim 12). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 and claims 20-29 which depend from claim 1 are rejected because, the invention appears to employ novel recombinant host cells (*E.coli* DSM 12197). Since the host cells are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences in the host cells are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmids. The specification does not disclose a

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repeatable process to obtain the vectors or the recombinant host cells and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the organisms but there is no indication in the specification as to public availability. As the deposit was made under the terms of the Budapest Treaty, an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

7. Claims 1, 9 and claims 3, 9-11, 13, 14 and claims 20-29 which depend from claim 1 and 9 respectively, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mannase enzyme from a *Bacillus* strain, does not reasonably provide enablement for any mannase from any source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1 and 9 are so broad as to encompass any mannase enzyme from any source or any recombinant mannase enzyme from any source which is 65% identical to SEQ ID NO:2 in its amino acid sequence. The scope of the claims is not commensurate with the enablement

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provided by the disclosure with regard to the extremely large number of mannase enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and to obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the mannase enzyme of the genus *Bacillus*.

While enzyme isolation techniques and recombinant techniques are known, it is not routine in the art to screen multiple sources, multiple substitutions, or multiple modifications, as encompassed by the instant claims, and the reasonable expectation of success in obtaining the desired enzyme are limited due to the complexity of the huge number of microorganisms, mammals, fungi and plants that need to be analyzed and the result of such isolation from an extremely large number of sources is unpredictable.

The specification does not support the broad scope of the claims which encompass all any mannase enzyme of any bacteria, mammal, plant or fungi because the specification does not establish: (A) a rational and predictable scheme for isolation and characterization of any mannase from any given source with an expectation of obtaining the desired biological activity and function; (B) regions of the protein structure which may be modified without effecting the mannase activity; (C) the general tolerance of mannase enzymes to modification and extent of

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such tolerance; and (D) the specification provides insufficient guidance as to which of the infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any mannase enzyme of any microorganism or mammal or fungi or plant which is 65% identical in its amino acid sequence to SEQ ID NO:2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

8. Claims 1, 9 and claims 2-3, 9-11, 13, 14 and claims 20-29 which depend from claim 1 and 9 respectively, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 9 are directed to polypeptides which are 65% identical to SEQ ID NO:2 and polypeptide fragments corresponding to portions of the sequence of SEQ ID NO:2. Claims 1, 9 are rejected under this section of 35 USC 112 because the claims are directed to a genus of

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polypeptides derived from SEQ ID NO:2 including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in SEQ ID NO:2 and fragments of SEQ ID NO:2 that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:2 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure and function of all the polypeptide sequences derived from SEQ ID NO:2, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have an enhanced mannase activity or no mannase activity. Therefore many structurally and functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the phrase "encodable by" in parts (a) and (c). Without a clear definition to the above phrase in the specification, it is unclear to the Examiner as to what applicants mean by the term "encodable". Amending the claim to recite as "encoded by" would overcome this rejection.

11. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the phrase "derivable from". Without a clear definition to the above phrase in the specification, it is unclear to the Examiner as to what applicants mean by the term "derivable". As such there appears to be an ambiguity regarding the availability of this enzyme from the said strain of *Bacillus* as if under normal conditions the bacterium does not make the enzyme, however, under certain conditions the enzyme is derivable from the above strain. Amending the claim to recite "obtained from" would overcome this rejection.

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12. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the phrase "and/or" between parts (ii) and (iii). It is not clear to the Examiner as to what is the exact limitation of the claim. Amending the claim to include either only "and" or only "or" would overcome this rejection.

13. Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 24 and 25 are drawn to cleaning composition comprising an amylase (claim 24) and cellulase, protease etc. It is not clear to the Examiner as to how these enzymes differ from the enzymes of the cleaning composition of claim 21 on which the above claims depend on.

14. Claim 29 recites the limitation "fabric softening composition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-2, 9-11, 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Yoshida et al. (PIR Accession NO. JE0134, dated 6-3-1998) or rejected under 35 U.S.C. 102(b) as being anticipated by Akino et al. (PIR Accession NO. A37219, dated 12-30-1991). This rejection is based upon the public availability of a printed publication. Claims 1-3, 9-11, 14 of the instant application are drawn to an isolated mannase enzyme obtained from a *Bacillus* sp. which has an amino acid sequence that is at least 65% identical to the amino acids 31-300 of SEQ ID NO:2, or a fragment of the same. Yoshida et al. disclose an identical enzyme derived from a *Bacillus* sp. which has more than 65% sequence identity with amino acids 31-300 of SEQ ID NO:2. Yoshida et al. Thus Yoshida et al. anticipate claims 1-2, 9-11, 14 of this application as written.

17. Claims 1-2, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Akino et al. (PIR Accession NO. A37219, dated 12-30-1991). This rejection is based upon the public availability of a printed publication. Claims 1-2, 14 of the instant application are drawn to an isolated mannase enzyme obtained from a *Bacillus* sp. which has an amino acid sequence that is at least 65% identical to the amino acids 31-300 of SEQ ID NO:2, or a fragment of the same. Akino et al. disclose a mannase, whose fragment amino acid sequence matches with a fragment of SEQ ID NO:2. Thus Akino et al. anticipate claims 1-3, 14 of this application as written.

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Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1-3, 9-11, 13, 14, 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mendoza et al. (World J. Microbiol. Biotechnol., 1994, Vol. 10:551-555) in view of Cuperus et al. (WO 95/35362, 12-28-1995). Claims 1-3, 9-11, 13, 14, 20-29 of the instant application are drawn to an isolated mannase enzyme obtained from a *Bacillus* sp. which has an amino acid sequence that is at least 65% identical to the amino acids 31-300 of SEQ ID NO:2, or a fragment of the same, and which has an activity of at least 60% in the pH range 7.5-10, measured at 40 C and a molecular weight of 34 ± 10 kDa. Furthermore claims are also directed to a purified form of the above enzyme and its use in cleaning compositions along with several other hydrolytic and proteolytic enzymes.

Mendoza et al. teach the purification of a mannase from a *Bacillus* sp. which has similar characteristics as that mentioned above for the instant mannase. The reference mannase has a molecular weight of 38 kDa which is within the range of 34 ± 10 kDa. It appears to have at least 60% activity in the pH range of 7.5-10 when measured at a temperature of 40° C (see figure 4, all panels). However, the reference does not teach the amino acid sequence of the polypeptide which is an inherent characteristic of any enzyme. Also, the reference does not teach the N-

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terminal amino acid sequence as that of the instant application. However, the claim as written does not indicate whether the N-terminal amino acid sequence is a limitation because of the use of "and/or" language. Furthermore, since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. The reference also does not teach the use of mannase in a cleaning composition either by itself or as a composition including other enzymes.

Cuperus et al. teach the use of mannase and other enzymes for cleaning by making cleaning compositions. It would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Mendoza et al. who teach a mannase enzyme isolated from a *Bacillus* sp. with that of Cuperus et al. to develop a cleaning composition which has activity in a wide range of pH and temperature conditions. One skilled in the art would be motivated to do this in order to develop a cleaning composition that is capable of cleaning a surface under a range of conditions. One would have a reasonable expectation of success since Mendoza et al. provide a purified enzyme and Cuperus et al. teach a reliable and time-tested method of use of the enzyme.

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Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao

December 26, 2000


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